

1 ABSTRACT

2 **Background:** Community pharmacy practice in the Kingdom of Saudi Arabia (KSA) faces many
3 challenges. In KSA, there is a lack of empirical research about medication safety in this setting.

4 **Objective:** To explore the safety problems associated with medication supply from community
5 pharmacies in KSA and compare different stakeholder perspectives.

Methods: Four focus groups and individual interviews were conducted in Riyadh, KSA, in February-May 2013. All group discussions were recorded, transcribed and translated from Arabic into English, except the professional group, which was conducted in English. Thematic analysis was performed using the Human Factors Framework (HFF).

Results: The groups comprised “professionals” (n=8; one female), community pharmacists (n=4; all male) and two pharmacy user groups (females, n=11 and males, n=8). Medication safety problems identified were categorised into nine categories representing the HFF. Seven main themes were identified from these categories: commercial pressure on community pharmacy; illegal supply of prescription medication; lack of enforcement of regulations; the healthcare system; self-medication; patient trust in pharmacists: and communication failure. Themes that emerged only from the “professionals” and community pharmacists were the different role of the regulatory organisations and the reasons behind lack of enforcement, while the community pharmacist group focused on the relationship between owners and managers. Pharmacy users expressed a need for information about medication and that the primary role of the pharmacist should be as an information provider. Furthermore, they perceived pharmacists to be vendors rather than healthcare professionals.

22 **Conclusion:** Many medication safety problems were identified, attributable to individuals
23 (patient, pharmacist), pharmacy and organisational factors. These results will be used to
24 develop interventions to improve medication safety.

26 BACKGROUND

27 The World Health Organisation has highlighted safety in primary care as an international
28 challenge.[1] In primary healthcare, adverse drug events (ADEs) are reported to occur in 25% of
29 outpatients, almost half of which (11%) are preventable.[2] Research undertaken in the
30 community pharmacy setting has mostly focused on detecting and measuring medication errors
31 and near misses.[3]

32 Studies in the Kingdom of Saudi Arabia (KSA) have shown high levels of hospital admissions
33 associated with drug-related problems (DRPs), of which the most common causes were ADEs, a
34 failure to receive medication and medication non-compliance.[4,5] A range of challenges to
35 medication safety in KSA were identified: limited use of technology; illegal supply of
36 prescription only medication (POM); communication gaps between healthcare institutions;
37 under-reporting of ADEs and communication barriers.[6] Studies in KSA have mainly
38 investigated the problems either from a pharmacist or a pharmacy user perspective using
39 mostly surveys.[7-11] No qualitative studies have been conducted with pharmacy users or
40 other stakeholders, such as policy makers and pharmacy owners.

41 The application of theory may help to understand patient safety problems and a number of
42 relevant frameworks exist. [12-17] The Human Factors Framework (HFF) has potential to
43 enhance clinical performance by understanding the effects of factors such as teamwork, tasks,
44 equipment, workspace, culture and organisation on human behaviour and abilities, and
45 applying insights to clinical settings. [14-18] The HFF aids understanding of people's
46 capabilities and limitations, allowing design of better systems. It is a recognised tool to reduce
47 medication error rates or mitigate adverse medication effects. [12]

48 The purpose of our study was to explore and compare different stakeholder perspectives
49 regarding the safety problems associated with medication supply from community pharmacies
50 in KSA using the HFF. The stakeholders for whom medication safety is important include service
51 users, community pharmacists, pharmacy owners, as well as representatives from legal and
52 regulatory authorities.

53 METHODS

54 This qualitative study comprised a series of focus groups and interviews. Focus groups were
55 conducted with different stakeholders: healthcare professionals; community pharmacists; and
56 pharmacy users. Individual interviews were conducted with community pharmacists only.

Sampling and recruitment

The study was conducted in Riyadh, the capital of KSA. The healthcare professional group (PG) was recruited purposively, identified through professional and personal networks.

The community pharmacist group (CPG) was recruited using purposive, convenience and snowballing methods. Personal visits to pharmacies and telephone calls were made to invite participants. Telephone interviews were offered only to community pharmacists who could not attend the focus group due to job commitments.

Pharmacy users aged 18 and older were eligible to participate. Different recruitment strategies were adopted to reflect the cultural constraints in Saudi society. For the female pharmacy user group (FPG), community centres and sites for social activities were sought in Riyadh. A non-profit childcare association providing free weekly parenting courses in community centres was identified, to recruit female attendees who were of various ages and educational backgrounds. For the male pharmacy user group (MPG), an announcement about a support group for caregivers of Alzheimer patients was sent via Twitter from the Alzheimer Society account. This support group is held once a month in a private training centre. The researcher (LJ) visited one of these support group meetings for recruitment purposes.

All potential participants, irrespective of group, received an invitation letter and study information sheet. A consent form was provided by e-mail or personally, one week prior to the focus group. Each participant signed an individual informed consent statement prior to the commencement of the focus groups.

Data collection

The focus groups were conducted using semi-structured topic guides (Supplementary Material) (one for FPG and MPG and one for the PG and CPG), which were informed by the literature and the HFF. Data were collected on participants' age, gender, and education background and practice experience. The PG was moderated by MW. The remaining focus groups were moderated by LJ, with SA in attendance. Before undertaking the group discussions, a pilot focus group was conducted with first year undergraduate pharmacy students to test questions and data collection methods.

Research ethics

This study was completed as part of the first author's PhD thesis who undertook specific training regarding conducting and analysing qualitative research. Approval for this study was received from The College Ethics Review Board, University of Aberdeen, UK.

Data management and analysis

Each focus group was audio-recorded and transcribed verbatim by LJ. The groups were undertaken in Arabic and the transcripts were then translated from Arabic into English, except for the PG group, which was conducted in English. A member of the research team (LJ) undertook the translation; a professional translator checked the accuracy of the translation. The analysis used a priori and emergent codes; codes were identified independently from the data by two researchers (LJ, MW). [19] The codes were then categorised using the HFF. Two coding (Supplementary Material) indices were generated based on commonality of codes: one was used to code the transcripts of the PG and CPG, while the other was for the pharmacy user groups. The coding for each focus group was checked for accuracy by a second researcher (MW, SA, or PK). A comparative analysis was then conducted to identify commonality, differences and relationships through the themes categorised in the HFF to identify mega themes. [19] This study was conducted and reported in accordance with COnsolidated Criteria for Reporting Qualitative Studies (COREQ). [20]

RESULTS

In total, 35 individuals participated across four focus groups and four interviews (Table 1). All data collection was undertaken between February and May, 2013. The PG (n=8) comprised representatives from several organisations responsible for regulating pharmacists and pharmacy practice, as well as pharmacy academics and pharmacy owners. All participants in the PG were Saud nationals. The CPG participants were Egyptian (n=3) and Yemeni (n=1).

Table 1 Characteristics of participants

Focus Groups	Professionals	Community pharmacists		Pharmacy users	
	Focus group	Focus group	Individual Interviews	Female focus group	Male focus group
Total Individuals invited	15	75	5	15	9
Number of participants (male)	8 (7)	4 (4*)	4 (4*)	11 (0)	8 (8)
Age years (SD)	40.6 (7.1)	34.7 (10.6)	37.7 (13.8)	33.5 (5.8)	34 (5.9)
Duration of interaction (minutes)	104	86	19.2 (3) Mean (SD)	62	89

Only males are permitted to work in the community pharmacy setting in KSA.

SD Standard deviation

The data were categorised into nine categories representing the HFF (Table 2). From these categories, seven main themes were identified (Table 3). Example of similarities and differences of themes across all groups are presented in (Table 4). The themes are described in the text

supported by anonymised, verbatim quotes from participants' narratives (which are written in italics and quotation marks). To illustrate which focus group generated the identified themes, results are referred to below by the following letters: professionals (PG); community pharmacist (CPG); female pharmacy users groups (FPG) and male pharmacy users groups (MPG), followed by a hyphen and the number of the participant, e.g. PG-1 is participant 1 in the PG, etc. For further quotes in the Supplementary Material.

Table 2 Human Factors and sub-themes identified in the Focus groups

Human factors category	Sub-themes
External factors	Commercial pressure and commercialism Regulations and regulators The healthcare system in Kingdom of Saudi Arabia
Organisational and management factors	Pharmacy owners' and managers' roles Lack of patient database in community pharmacies
Work environment	Pharmacist working hours Type of pharmacy and its effect on medication safety
Team factors	Physician prescribing behaviour Communication between pharmacists and physicians
Individual factors: Pharmacists	Pharmacist competence and clinical skills Pharmacist adherence to law and regulations Pharmacist role as perceived by participants
Task factors	Illegal Supply of prescription-only medication to patients. Medication storage and transportation in community pharmacies Generic substitution
Communication and information exchange	Patient-pharmacist communication Factors affecting communication exchange Type of information requested by patients from pharmacists Patient medication information source Pharmacist versus physician information
Patient	Patient characteristics: risk factors for medication safety problems Patient trust in pharmacists Patient trust in physicians Patient beliefs and perceptions Patients' behaviour Patient role and responsibility towards medication safety
Medication	Medicines associated with the risk Medication availability and shortage Counterfeit medication
Others	Patient experiences with drug-drug interaction and adverse drug events Comparison with other countries regarding practice and quality of medication.

131 **Table 3** Emergent themes identified

Emergent themes	Sub-themes
Commercialism and commercial pressure on community pharmacies in kingdom of Saudi Arabia	<p>External factors</p> <ul style="list-style-type: none"> • Commercial pressure and commercialism • Healthcare system role in commercialism <p>Organisational and management factors</p> <ul style="list-style-type: none"> • The role of pharmacy owners and managers <p>Work environment</p> <ul style="list-style-type: none"> • Type of pharmacy and its effect on medication safety • Pharmacist working hours • Low salaries <p>Team factors</p> <ul style="list-style-type: none"> • Physician prescribing behaviour <p>Task factors</p> <ul style="list-style-type: none"> • Patient counselling • Generic substitution • Medication storage and transportation <p>Patient factors</p> <ul style="list-style-type: none"> • Patient belief and perception about the business oriented practice • Patient behaviour
Illegal supply of prescription medication by pharmacist	<p>External factors</p> <p>Individual factors: pharmacist</p> <p>Patient factors</p>
Lack of enforcement of regulations	<p>External factors</p> <ul style="list-style-type: none"> • Regulations and regulators <p>Individual factors: pharmacist</p> <ul style="list-style-type: none"> • Pharmacist adherence to law and regulations <p>Patient factors</p> <ul style="list-style-type: none"> • Patient pressure on pharmacists to commit a misconduct <p>Medication</p> <ul style="list-style-type: none"> • Counterfeit medication as consequence
Healthcare system in kingdom of Saudi Arabia	<p>External factors</p> <ul style="list-style-type: none"> • The fragmented healthcare system • Lack of patient database in community pharmacies <p>Organisational and management factors</p> <ul style="list-style-type: none"> • Implementation of technology in community pharmacy
Patient medication-taking behaviour	<ul style="list-style-type: none"> • Self-medication • Sharing medication • Adherence to medication
Patient trust in pharmacists	No subthemes identified
Communication and information exchange	<ul style="list-style-type: none"> • Patient–pharmacist communication • Patient medication information source • Factors affecting communication exchange • Type of information requested by patients from pharmacists • Information received from pharmacist information compared to information received from physician <p>Team factors</p> <ul style="list-style-type: none"> • Communication between pharmacists and physicians

132

Table 4 Example of similarities and differences of themes across all groups

Theme	Professionals	Pharmacists	Pharmacy users	
			Male	Female
Commercialism and commercial pressure on pharmacists.	✓	✓	✓	✓
Self-diagnosing and self-medication.	✓	✓	✓	✓
Lack of enforcement of regulations.	✓	✓	✓	✓
Illegal supply of prescription medication.	✓	✓	✓	✓
Fragmented healthcare system.	✓	✓	✓	
Patient trust in pharmacist.		✓	✓	✓
The primary role of the pharmacist should be as an information provider.		✓	✓	✓
Communication failure between pharmacists and patients.	✓	✓		
The need for information			✓	✓
Perception of pharmacists as salesmen rather than healthcare professionals.			✓	✓
Pharmacy design and its effect on counselling.			✓	✓

Commercialism and commercial pressure

Commercialism in community pharmacy practice in KSA emerged as a theme in all groups. Participants identified factors and consequences of commercialism on patient safety. These factors are presented here according to the HFF: external; organisational; work environment; team; task; and patient factors.

External factors

Participants across all groups except the FPG discussed the role of pharmaceutical companies in creating commercial pressure by paying bonuses to physicians and community pharmacists to prescribe and dispense certain medications, which may not be needed.

"In our country, the pharmacist gives you the medication that is suitable to him or the medication for which he receives a commission, you go to the pharmacist you say you have a headache he gives you Fevadol instead of Panadol [generic substitute] for example he gives you the medication that suits you, who he is an agent for it or gives him a commission for. Even in clinics, the representative of the company comes to the physician and gives him the new medications with tickets and gifts and the physician prescribes the medications." (MPG-5)

The PG participants suggested that recent rapid increases in the number of pharmacies, combined with their proximity to each other, contributed to increased competition between

153 them. This pressured pharmacists to illegally supply POM to to maintain their business and
154 retain consumers/patients.

155 *"It is not logical that I will not sell the medication without [prescription], while my*
156 *neighbour is selling it without [prescription]. I would go broke."* (PG-2)

157 The PG participants also suggested that the pharmaceutical industry restricted certain generic
158 medicines to increase sales of newer, more expensive brands, contributing to medication
159 shortages.

160 *"I comment on availability issues. Some of it [is] truly shortages, and some of it is*
161 *[not]. Unfortunately, this is a commercial business. I know some pharmacies will*
162 *not introduce a product without getting fees or getting huge bonuses from the*
163 *company. The company will not be able to sell it that is again with the law how far*
164 *you can enforce the law on community pharmacy?"* (PG-4)
165

166 *Organisational and managerial factors*

167 Participants in the CPG believed that pressure from owners and managers of community
168 pharmacies contributed to creating a profit-oriented rather than patient-oriented pharmacy
169 practice.

170 *"Maybe he is being pushed by his managers to be money making..."* (MPG-3)

171 *Work environment*

172 The CPG, FPG and MPG perceived community pharmacies owned by commercial companies
173 (also known as chain pharmacies) to be safer than independent pharmacies. They explained
174 that chain pharmacies have more rigorous internal regulatory systems, offer training
175 programmes for the pharmacists and have lower individual workload owing to investment in
176 technology. Interestingly, the public group believed that independent pharmacies are less
177 affected than chain pharmacies by commercial pressures.

178
179 *"[Chain pharmacies] have a policy that we will not violate the law and the*
180 *patient will find what he wants; this is the mistake of the patient"* (CPG-1)
181

182 The CPG and MPG participants discussed long working hours and their effect on practice. They
183 believed that the long working hours were related to the owner's interest in maintaining their
184 profit.

185 *"He has long working hours and that leads many pharmacists to not refresh*
186 *their information, ...there is no role for the Ministry to update your*

187 *information. For example, the pharmacist (CPG-4) graduated in 1986 and*
188 *necessarily many improvements have taken place since that time.” (CPG-2)*
189

190 *Team factors*

191 The PG also acknowledged that pharmaceutical companies influence the prescribing behaviour
192 of physicians through advertising and financial incentives, which tends to result in
193 overprescribing.

194 *“The quality of the physician usually they come with very low salaries but*
195 *depending on the commissioning they get from the companies and still they have*
196 *the commission we see the kind of prescription which is very weak even our*
197 *pharmacists discover these mistakes it happens with me a lot so due to this kind of*
198 *this low educated physicians.” (PG-2)*

199 *Task factors*

200 Participants in the pharmacy user groups felt that commercial pressure on pharmacists affected
201 the advice and information provided. They suggested that advice given by the community
202 pharmacists was for marketing purposes and not tailored to patients’ actual needs.

203 *“My problem is always that when I go, they give me the best and the latest on the market,*
204 *that is to say, they do not give me the one appropriate for me. The problem is that they do*
205 *not try to learn whether it is appropriate or not.” (FPG-1)*

206

207 Pharmacists substituting a prescribed branded medication with a different form of the same
208 active substance (generic substitution) was an emerging theme across all groups. The PG stated
209 that the problem is that community pharmacists provide medication alternatives to patients
210 based on financial incentives and commission rather than patient benefit.

211 *“If you go to a pharmacist and you say you have a mild or minor ailment and*
212 *ask for a prescription, you have two products [options] one product will fit you,*
213 *but that does not have a bonus, the other product has a bonus.” (PG-4)*
214

215 Participants discussed the problem of inappropriate storage conditions for medicines in
216 community pharmacies and warehouses, attributed by some participants in the PG and
217 pharmacy users’ groups to a desire to cut costs.

218 *“It is a matter of saving electricity just like groceries. At night, they disconnect*
219 *the refrigerator containing milk to save electricity, and when they come back*
220 *in the morning, they turn on the electricity.” (MPG-4)*

221

222 **Patient factors**

223 On a number of occasions, participants in the PG as well as the pharmacy user groups referred
224 to the way that patients perceive the community pharmacy as a grocery shop.

225 *"We look in KSA at a pharmacy as a store ... It should be a service, not a store."*

226 (PG -3)

227 However, perceptions of pharmacists were highly varied amongst participants in the pharmacy
228 user groups. Some considered pharmacists to be salesmen, while others perceived them as
229 healthcare professionals.

230 *"He is interested mainly in collecting money." (FPG-3)*

231

232 *"People think that he is a seller, but he is well qualified in term of education. He*
233 *spent a long time studying and understands drug composition maybe more than*
234 *the physicians." (FPG -2)*

235 Participants in the pharmacy user groups acknowledged that they buy whatever they want from
236 the pharmacy acting as a "consumer."

237 *"As a consumer, I go to the pharmacy and take the antibiotic I want, I can take*
238 *whatever medication I want without prescription." (MPG-5)*

239

240 **Illegal supply of prescription medication by pharmacists**

241 *External factors*

242 The PG suggested many reasons to explain the illegal supply of POM which they described as a
243 violation of regulations, including patients perceiving medication as a commodity and patients
244 who are stable on medication visiting the community pharmacy to refill their POM without a
245 prescription. In addition, they suggested other "external factors" that were highlighted
246 previously, such as the limited capacity of the healthcare system, the lack of regulation
247 enforcement and commercial pressures.

248 *"...So now you have lack of enforcement of the law, huge pharmacies, huge*
249 *number of non-Saudi pharmacists and you can say there is nobody in charge*
250 *that lead to where people are treating medications as a commodity rather*
251 *than special products that need attention..." (PG-4)*

252

253 However, such practices were identified as a cause of hospital admission by the PG. Antibiotics
254 were given as an example of medication supplied illegally in all groups, and participants in the
255 CPG provided other examples, such as hypnotics and antidepressants.

256 *Individual factors: pharmacists*

257 Participants in the CPG acknowledged that they sometimes illegally supply POM and provided
258 justifications for their actions.

259 *"I dispense everything; I am a pharmacist regardless of the laws, when you have a*
260 *patient in front of you needing to be treated it would be difficult especially if the*
261 *patient is poor and needs assistance you do not help him; for humanity" (CPG-4)*
262

263 **Lack of enforcement of regulations**

264 Lack of enforcement of regulations emerged as a theme in all groups. Factors and consequences
265 of lack of enforcement of regulations identified in this study are presented in this section
266 according to the HFF: external; pharmacist and patient.

267 *External factors*

268 Across all groups, participants agreed that the Saudi government issued regulations to uphold
269 the quality of community pharmacy practice. Participants also identified the roles played by
270 different regulatory bodies in inspecting and controlling medication supply. However, they all
271 agreed that governmental regulations are not enforced effectively.

272 *"...There is a complete difference between the law and the reality." (CPG-2)*
273

274 The PG suggested that there were too few governmental inspectors in relation to the large
275 number of community pharmacies. Furthermore, the community pharmacists perceived
276 inspectors to be inadequately trained.

277 *"...The number of inspectors who are supposed to enforce the law have almost*
278 *declined you don't have the same growth in the number of inspectors as you have in*
279 *the number of the pharmacies...so that automatically leads to the lack of enforcement*
280 *of the law so now you have lack of enforcement of the law, huge pharmacies, huge*
281 *number of expatriates pharmacists and you can say there is nobody in charge." (PG-*
282 *4)*
283

284 *Individual factors: pharmacists*

285 Pharmacists' adherence to regulations emerged during the discussion. One participant in the PG
286 group believed that all pharmacists would like to adhere to the law.

287 *"No professional pharmacist will like to break the law..." (PG-4)*

288 Conversely, the CPG admitted violating certain pharmacy practice regulations. There were
289 examples of pharmacist violations given in all the focus groups, such as illegal supply of POM,

290 inappropriate storage conditions of medication, pharmacists working without licence, and
291 supplying medication without a label.

292 *"The air conditioning is not working, the expiry date of the medicine ... also they store*
293 *medicines outside the refrigerator. We found some big problems we saw the*
294 *technician dispensing the medicine they are not allowed to dispense the medication*
295 *also find the pharmacist work without licence this is a big problem in the pharmacy."*
296 (PG-8)
297

298 *Patients factors*

299 Patients also influence pharmacists' behaviour in terms of not adhering to regulations due to
300 pressurising pharmacists to illegally supply medications. Participants in the CPG said that they
301 find themselves compelled to supply medication to patients in these situations, despite this
302 being prohibited by law.

303 *"Originally, it is prohibited by the Ministry of Health to dispense antibiotic as a*
304 *strip and if this is done it would be a violation and in case of not dispensing them in*
305 *this form, the patient will go to a second, third and fourth pharmacy until he finds*
306 *what he wants"* (CPG-1)
307

308 **The healthcare system in Kingdom of Saudi Arabia**

309 Participants in all groups discussed factors related to the healthcare system and their impact on
310 medication safety in Saudi Arabia. These factors are presented here according to the HFF:
311 external and organisational factors.

312 *External factors*

313 The structure of the Saudi healthcare system was an emerging theme. The PG and FPGs
314 discussed the fragmented healthcare system. Patients visiting different physicians for the same
315 medical problem and a lack of continuity in care are the results of the fragmented provision of
316 healthcare that could lead to medication duplication and compromised medication safety.

317 *"For example, the patient went to a physician who prescribed him Amlor*
318 *[Amlopidine] and then went to another physician who prescribed him Amlopine*
319 *[Amlopidine]. He imagined that they are different medications and took both."*
320 (CPG-4)
321

322 The PG discussed the limited capacity of the healthcare system and its inability to meet the
323 increasing healthcare needs of the population. They suggested that community pharmacies
324 could play a role in caring for patients to minimise the pressure on other healthcare facilities.

325 *"Community pharmacy should work as primary centres ... take for example diabetic*
326 *patient whatever the government invest and put amount of money in hospitals and*
327 *primary care they will not be able to manage the whole diabetic population. They are*
328 *huge [the diabetic population] so if you add hypertensive patients and asthmatic*
329 *patient they are huge."* (PG-4)
330

331 Participants also discussed the lack of a patient database and filing system in community
332 pharmacies: they perceived an electronic patient database with relevant medical information
333 accessible to community pharmacists to be an important factor in medication safety.

334 *"There should be a special file for each patient in each pharmacy, not only in the hospital."*
335 (CPG-1)
336

337 *Organisational and management factors*

338 Participants suggested that solving the problem starts with the Saudi Ministry of Health, which
339 should establish a national electronic health records database. The need to implement
340 technologies such as electronic prescribing and to utilise drug information software, was
341 discussed in both the PG and the CPG.

342 **Patient medication taking behaviour**

343 Patients' accounts of behaviours such as self-medication, sharing medication and adherence to
344 medication emerged. Self-medication in the context of this study is the selection and use of
345 medicines by individuals to treat self-recognized conditions or symptoms with POM or over the
346 counter (OTC) medication. Participants in all groups agreed that self-medication is common in
347 KSA.

348 *"I went to the pharmacy and said [something] and then some medications were*
349 *given to me, that is, we are treating ourselves."* (MPG-1)

350
351 The MPG proposed several reasons for self-medication such as cultural influences, the
352 accessibility of medication, the large number of community pharmacies, and patients' previous
353 experiences with a medication.

354 The CPG highlighted that patients even self-medicate with antidepressants without consulting a
355 physician. They were also aware of medication abuse such as the use of steroids for weight gain
356 and skin whitening.

357 *"Most people request Seroxa [antidepressant], and a segment of women take it due*
358 *to marriage pressures. They take psychiatric medicines as a tonic that enables them*
359 *to deal with the community in a better way." (I-3)*
360

361 Sharing medication emerged as a theme across the CPG, FPG and MPG. Participants discussed
362 sharing medication such as vitamins, painkillers and antibiotics with family members: *"As fruits*
363 *in the refrigerator."* (MPG-5)

364 *"Sometimes I think that the factor is economics and he doesn't want to pay for*
365 *something he doesn't want to continue using." (CPG-1)*
366

367 Patients do not adhere to their medications and do not follow instructions provided by
368 pharmacists as participants in the CPG and MPG described.

369 *"frankly, I never completed the period of the course" (MPG-3)*
370

371 The patient's role in medication safety was discussed in all groups, and there was general
372 agreement of the importance of educating patients.

373 **Patient trust in the pharmacist**

374 Patient trust in the pharmacist emerged in the CPG and pharmacy user groups. Participants in
375 the pharmacy user groups identified several factors that affect this trust, such as pharmacists'
376 age, an existing relationship with the patient, provision of advice, pharmacist nationality, and
377 knowledge of the sector in which the pharmacist worked, e.g. governmental or private. Some
378 participants perceived pharmacists having low levels of competence due to their non-Saudi
379 nationality, especially regarding recognising trade names of medication. Another reason for lack
380 of trust was due to the perception that pharmacists are business-oriented rather than patient-
381 oriented.

382 *"He has knowledge; he is old and calm, and he knows that I am coming for a*
383 *consultation. I tell him the physician prescribed this and this. He knows me, and I*
384 *buy some of the things. He knows my face, and he counsels me and gives me some of*
385 *his time. He says, 'no this is that and this is good', and he gives me alternatives. He*
386 *gives me advice. He is next to my home, and I trust his opinion." (MPG-4)*
387

388 There was disagreement in the MPG that providing generic alternatives increases patients' trust
389 in pharmacists. Participants in the CPG identified several factors that cause patients to lose
390 confidence in the pharmacist. For example, when the pharmacist spends more time reading the
391 prescription due to bad physician handwriting or incomplete patient information, which leads
392 pharmacists to ask the patient more questions. The CPG believed that patients trust physicians
393 more than pharmacists.

394 *"I may receive a prescription in which the age and the diagnosis are not mentioned*
395 *and what is only mentioned is the name. In order to dispense the medication, I ask*
396 *many questions, I ask until I know the meant medication. Asking many questions*
397 *results in the loss of confidence between the patient and me. My questions are*
398 *meaningful since I concentrate on certain points."* (CPG-3)

399 **Communication and information exchange**

400 Pharmacy users and the CPG discussed poor communication between pharmacists and patients,
401 including the question of who should initiate communication.

402 *"What I notice is that they take the prescription and put it on the counter, and that is*
403 *all. They do not even say hello."* (MPG-1)

404
405 Pharmacy users expressed a need for information about medication and that the primary role of
406 the pharmacist should be as information provider.

407 Barriers to effective communication identified by participants in all groups included language,
408 culture, education, gender, having a third person (family member or friend) assigned by the
409 patient to obtain the medication from the pharmacy, pharmacy layout and pharmacists'
410 workload.

411 *"I came across someone who didn't know whether the medication was for*
412 *constipation or diarrhoea. He said he wanted something for diarrhoea. The*
413 *matter is that he didn't want something for diarrhoea; he wanted something to*
414 *cause diarrhoea. In brief, language has an effect."* (CPG-4)

415
416 The CPG suggested that patients' ability to access medication information from other sources,
417 such as the internet or friends, and the role of TV advertising, can cause problems when
418 communicating with a patient, as they come to the pharmacy influenced by information from
419 these different sources.

420 *"Patients come to me and say, 'I read that this drug is dangerous'. I ask him,*
421 *'Where did you read that?' and he says, 'The internet'."* (CPG-3)

422

423 The CPG also expressed concerns about the patient providing incomplete information or
424 wrongly expressing symptoms to the pharmacist. The PG and MPG agreed on the need for clear
425 and easily comprehensible information about medication in Arabic.

426 **DISCUSSION**

427 The study identified a range of major medication safety problems in community pharmacy in
428 KSA from a range of perspectives. The factors and circumstances that contribute to these
429 problems are complex and interact with each other.

Commonalities existed across groups, and unsurprisingly the PG identified problems at a systemic or regulatory level. For example, all groups discussed the lack of enforcement of regulations. The professionals provided the reasons behind this, debating the role and importance of each organisation involved in pharmacy practice. The community pharmacists discussed the day-to-day problems that pharmacists face in terms of owners, patients and inspectors. The FPG, of whom the majority were mothers, shared their personal experiences with pharmacists and medications in their daily lives. The MPG also focused on regulations and systems and compared current practice in KSA with other countries, such as the UK and USA.

Most studies of medication safety in community pharmacy have considered only one aspect of safety, such as dispensing [21], prescribing errors [22-24] or workload [25]. Two studies have adopted holistic approaches to identify medication safety problems. [26,27] Phipps *et al.*, identified a number of social technical factors consistent with our findings, such as regulatory and legal factors, group norms, trust in pharmacists, profitability versus safety, quality assurance and workspace, and collaboration between prescribers and patients. [27]

Commercialisation of pharmacy practice in this study was attributed to corporatisation, increased numbers of pharmacies, the absence of any governmental reimbursement and the lack of enforcement of regulations by regulatory bodies. Subsequently, some pharmacists illegally supply POMs, supply unnecessary medication or provide generic substitution based on profit not patient benefit. Community pharmacies generally operate as private businesses, thus the financial impact of any decisions made by community pharmacists is a concern that could potentially influence the attitude of pharmacists to service provision, for example the reporting of errors. [27] The Saudi pharmaceutical sector is the largest in the Gulf region, and has recently been growing by 4.7% annually. [28] There has been a six-fold increase in the number of community pharmacies in KSA over the past 30 years. [29] This huge market tends to promote the 'corporatisation' of pharmacies, as has happened in the UK, in which there is a change in ownership pattern from individuals to larger pharmacy chains. [30,31] Bush *et al.* describe the impacts – often negative - on the professional autonomy of pharmacists working in these big companies. [30]

This current study suggests that failure to enforce regulations creates an environment in which violations become routine practice. For example, lack of enforcement of regulations has been attributed in this study and others conducted in KSA to the illegal supply of POM. [7-10] There is a lack of studies exploring the association between violations in community pharmacy practice and enforcement of regulations. [32] Lowe and Montagu [33], reviewed regulatory frameworks in 24 low-income countries and many of the challenges described are similar to those identified

in this study, particularly in terms of fragmented pharmacy legislation and regulation, and insufficient numbers of inspectors. [33] Two randomized intervention studies reported the effect of enforcement of regulation on pharmacist compliance to regulations and improving services such as giving advice to customers and a decrease in the illegal supply of some medications. [34,35]

Self-medication was identified in this study as one factor contributing to medication safety in community pharmacy. Patients who self-medicate usually diagnose and treat themselves based on their own experience or that of family or friends, or information from the media and internet. One reason for self-medication identified here was that patients could not afford or wanted to avoid a physician visit. The main risks from self-medication identified previously include misuse, a potential delay in treating a serious condition, masking of symptoms of a serious condition through the use of a OTC medication, and drug interaction. [36,37] It is a cause for concern that most of the risks previously identified relate to self-medication with OTC medication, while self-medication with POM is present in KSA. [38]

Another important factor identified is the fragmented healthcare system in KSA. Healthcare delivery in KSA occurs in 'mixed market' systems, with care delivered both by government and private sector providers. [39,40] This allows patients to obtain healthcare from multiple healthcare providers, which has been associated with a number of medication safety problems, including duplicate interventions [41], multiple prescriptions, exposure to potential drug interactions [42], and high costs for patients and the government. [43,44] Given there are no patient medication records in Saudi community pharmacies, pharmacists will supply the prescribed medication to patients not knowing their other medication, potentially leading to medication duplication due to multiple prescriptions from multiple doctors.

The illegal supply of POM has been reported in many developing countries such as Mexico, China and also in other countries in the Middle East. [45-47] The main reasons identified in KSA were financial interests and the lack of enforcement of regulations. [7,8,11] Pharmacists in this current study admitted to the illegal supply of POM and provided several justifications, which were similar to findings from a qualitative study in India [48], that illegal supply of POMs is a form of "social work" to help poor patients who cannot afford a physician's visit. The Indian study also cited commercial interest and the lack of pharmacist knowledge as reasons for this behavior.[48]

The lack of communication between pharmacists and patients was identified as a medication safety problem. The importance of establishing two-way communication in identifying [49] and

preventing ADEs [50,51] has been previously documented.

An important determinant in establishing a relationship with a pharmacist identified in this study is trust in the pharmacist.[52] Participants were suspicious of pharmacists' motives and their interest in profit rather than patient care. This is consistent with the findings of a study in Ireland. [53]

Strategies to target these factors and develop systems that ensure safe use of medication within community pharmacies are needed at different levels.

Strength and limitations of the study

The study findings identified several categories of HFF that are relevant to the community pharmacy setting and provide a deeper understanding of community pharmacy practice, including reasons for specific behaviours, such as the illegal supply of POM. Another strength of the study is that all stakeholders were represented except general medical practitioners.

KSA is socially and culturally unique. As such, some factors identified in the current study may not apply elsewhere. However, many factors identified are likely to have resonance in many countries, for example pharmacist workload. [25] The number of participants in the CPG was small, due to the long working hours of community pharmacist. Supplementary telephone interviews helped to achieve data saturation; no new themes emerged in the telephone interviews. [54]

Participants were recruited from Riyadh, the capital of KSA, and opinions might not represent those of people across KSA. For example, problems relating to non-Arabic speakers may not be present in more rural areas. More than six million people live in Riyadh, 40% of whom are non-Saudi; this percentage is not the same in other regions. [55] Lastly the majority of participants had a college education, so less educated individuals were under-represented.

CONCLUSION

Community pharmacy has been shown in this study to be a complex system involving many interacting factors that influence medication safety. These factors were identified and categorised using the Human Factors Framework. Commercial pressures on the community pharmacy sector and community pharmacists, a failure to enforce regulations, the fragmented healthcare system and self-medication, are all factors that contribute to medication safety problems. Strategies are needed at different levels to target these factors and develop systems that ensure safe use of medication within community pharmacies.

528

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533 **Contributors**

534 LA, MW, SA and PK were involved in all stages of the study. LA drafted the article, and all
535 authors including KM and HF were involved in critical revisions and approved the final version.

536 **Competing Interests**

537 None

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541 **Ethical approval**

542 The College Ethics Review Board, University of Aberdeen, UK

543 **Data sharing statement**

544 Audiotapes, notes and unpublished data from this study are securely stored and only available
545 to Lobna Al Juffali.

546

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687 **Supplementary material**

688 **Appendix A**

689 **Topic Guide for focus group (Pharmacy user's)**

690

691 **Questions to be addressed during the focus group**

692 a. What does medication safety mean to you?

693 Probes: Your personal experience of problems (adverse effect reactions)

694 b. What medicines are safe?

695 Probes: Why do you think they are safe?

696 Probes: when you are familiar with a medicine does this makes it safe? How is that?

697 c. What medicines do you think are associated with risk?

698 Probes: Why do you think they are unsafe?

699 d. What medical conditions are most likely to cause problems with medicines?

700 e. What patients are most at risks from medication?

701 Probes: Age, Gender, pregnant women, lactating women, etc

702 f. What are the main problems that you can encounter in a community pharmacy in
703 terms of medication safety?

704 g. How could community pharmacists help people with their medicines?

705 Probes: your suggestions

706 h. Any comments

707

708

Topic Guide for focus group (Professionals)

Questions to be addressed during the focus group

a. What are the main medication safety concerns associated with medicines supplied from community pharmacies in Saudi Arabia?

Probes: Identify the problems and give examples from their point of view and experience.

b. Who are the patients most at risk from medication safety problems?

Probes: what are the medical conditions that have the highest risk to the patient?

Probes: who are the population who are at most risk (age, gender, etc)?

c. What types of medication are associated with safety problems in community pharmacy?

d. What are the factors that contribute to these problems?

e. How can community pharmacists prevent and manage these problems?

f. What other agencies, organisations could help to improve medication safety with medicines supplied from community pharmacies?

Probes: How could this is achieved?

g. Any other comments

733 **Appendix B**

734 **Coding index (expert and community pharmacist)**

735 **1. New prescription**

736 1.1 Refill of a prescription medication

737 1.1.1 With a prescription

738 1.1.2 Without a prescription

739 1.2 Self-medication

740 1.2.1 Internet

741 1.2.2 TV/ Advertisement

742 1.2.3 Family, Friends, neighbours

743 1.2.4 Based on previous experience

744

745 **2. Medication use process**

746 2.1 Prescribing

747 2.1.1 Prescriber

748 2.1.1.1 Lack of knowledge

749 2.1.1.2 Failure to communicate between pharmacist and prescriber

750 2.1.1.3 Unethical prescribing practices/violation of the law

751 2.1.2 Prescription

752 2.1.2.1 Prescription incomplete information or ambiguous

753 2.1.2.2 Handwriting

754 2.1.2.3 Prescribing error

755 2.2 Dispensing

756 2.2.1 Patient pressure to supply medication

757 2.2.2 Incomplete patient information

758 2.2.2.1 Patient medical history

759 2.2.2.2 Medication record

760 2.2.3 Dilemma between patient care and money (commercial pressure)

761 2.2.4 Labelling

762 2.2.5 Illegal supply of medications

763 2.2.5.1 Factors that contribute to illegal supply of medication

764 2.2.5.2 Common medications supplied without a prescription

765 2.2.5.3 consequences of supplying medication without prescription

766 2.2.6 Generic substitution

767 2.3 Pharmacist-patient communication

768 2.3.1 Language

769 2.3.2 Literacy

770 2.3.3 Cultural considerations

771 2.3.4 Third party communicating patient information (family member or

772 2.3.5 Inaccurate information (self-diagnosis)

773

774 2.4 Administration (Medication taking behaviour)

775 2.4.1 Sharing medication

776 2.4.2 Adherence

777	2.4.3	Drug abuse
778	2.4.4	Drug misuse
779		
780	2.5	Monitoring
781	2.5.1	No follow up
782	2.5.2	Reasons for no follow up
783	2.5.2.1	No computer system
784	2.5.2.2	Others
785		
786	3.	Medication
787	3.1	High alert medication
788	3.1.1	Analgesics
789	3.1.2	NSAIDS
790	3.1.3	Antibiotics
791	3.1.4	Cortisone
792	3.1.5	Control medication
793	3.1.6	Psychotherapeutic agents
794	3.1.7	Thyroxine
795	3.1.8	Weight management agents
796	3.1.9	Minoxidil
797	3.1.10	Vitamins
798	3.1.11	Hormonal replacement therapy
799	3.1.12	Warfarin
800	3.2	Other related medication problems
801	3.2.1	Medications with unimproved indications
802	3.2.2	Look alike, sound like medications
803	3.2.3	Counterfeit medications
804	3.2.4	Expiration date
805	3.2.5	Bar coding
806	3.2.6	Pricing
807	3.2.7	Medication shortage and availability
808		
809	3.3	Herbal medication
810	3.4	Medication distribution
811	3.4.1	Transportation
812	3.4.2	Storage
813	3.5	Medication related problem concerning patient outcome
814	3.5.1	Duplication of therapy
815	3.5.2	Adverse drug effects
816	3.5.3	Dosage regimen
817	3.5.3.1	Dose too high
818	3.5.3.2	Dose too low
819	3.5.4	Drug interaction
820	4.	Patient
821	4.1	Patient at risk of medication safety problems
822	4.1.1	Patient with chronic diseases
823	4.1.2	Patient with Allergies
824	4.1.3	Patients with poly pharmacy
825	4.1.4	Gender

826	4.1.4.1 Female
827	4.1.4.2 Male
828	4.1.5 Age
829	4.15.1 Paediatric
830	4.15.2 Geriatric
831	4.1.6 Education
832	4.1.7 Language
833	4.1.8 Patients with no insurance
834	4.2 Patient /public awareness of medication safety
835	4.3 Patient perception and attitude towards healthcare professional roles
836	4.3.1 Physician
837	4.3.2 Pharmacist
838	5 Pharmacist
839	5.1 Scientific knowledge of pharmacist
840	5.2 Continuing education/ training
841	5.3 The quality of practice/unprofessional practice
842	5.4 Nationality
843	5.5 Pharmacist assessment/ licensing
844	5.6 Working hours
845	5.7 Stress
846	5.8 Fatigue
847	5.9 Salary
848	5.10 Pharmacist perception of their role
849	5.10.1 Compounding
850	5.10.2 Providing clinical services
851	5.10.3 Other
852	6 Pharmacy
853	6.1 Reimbursement for pharmacy
854	6.2 Specialised pharmacy for each population (disease)
855	6.3 Type of pharmacy
856	6.3.1 Independent
857	6.3.2 Chain pharmacy
858	6.4 Location ,distribution and number
859	6.5 Pharmacy owners/managers
860	6.6 The use of technology
861	6.6.1 Patient databases
862	6.6.2 Drug information software's
863	7 Organisations and systems
864	7.1 Regulators
865	7.1.1 Role of the Ministry of Health
866	7.1.2 Role of Saudi Food and Drug Authority
867	7.1.3 Role of other organisations
868	7.2 Role of Universities
869	7.3 Pharmaceutical companies and manufactures
870	7.4 Accreditation
871	7.5 Punishing and rewarding system
872	7.6 International Organization for Standardization
873	7.7 Regulation for pharmacy practice

874 7.7.1 The availability of regulation
875 7.7.2 Lack of enforcement of regulation
876 7.8 Inspectors
877 7.8.1 The qualifications of inspectors
878 7.8.2 Number of inspectors
879 7.8.3 Relationship between pharmacist and inspectors
880 7.9 Insurance
881 7.10 Patient filling system

882 **8 Commercial pressure**

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898 **Coding index (Pharmacy users)**

899 **1 Patient** (related to the patient characteristics and others)

900

901 1.1 Patient at risk of medication safety problems

902 1.1.1 Patient with chronic diseases

903 1.1.2 Patient with Allergies

904 1.1.3 Patients with serious operations

905 1.1.4 Patients with poly pharmacy

906 1.1.5 Patients with kidney problems

907 1.1.6 Patients with liver problems

908 1.1.7 Gender

909 1.1.7.1 Female

910 1.1.7.1.1 Pregnant

911 1.1.7.1.2 Hormones

912 1.1.7.1.3 More prone to disease

913 1.1.7.2 Male

914 1.1.8 Age

915 1.1.8.1 Paediatric

916 1.1.8.2 Geriatric

917 1.1.8.2.1 Bed ridden patients

918 1.1.9 Education

919 1.1.9.1 Patients

920 1.1.9.2 Care givers

921

922 1.2 Patients perceptions and believes

923 1.2.1 The medication is safe if it is written in the package insert that it is safe

924 1.2.2 Effective medicine are prescribed by the physician

925 1.2.3 Medications prescribe by the physician are safe

926 1.2.4 Illegal supply of medication by pharmacist are risky

927 1.2.5 Community pharmacies are not safe

928 1.2.6 Intervention of pharmacist is a must

929 1.2.7 Antibiotics has to be used as directed

930 1.2.8 Certain disease must be treated and others not important

931 1.2.9 Pharmacies are shops, groceries (for business)

932 1.2.10 Patient risk perception

933 1.2.10.1 Based on information provided

934 1.2.10.2 According to setting (hospital vs. community pharmacy)

935 1.2.10.3 Different routes are associated with different risks

936

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938 1.3 Patient /public awareness of medication safety

939 1.3.1 Patient responsibility and role

940 1.3.2 Patient awareness of regulations

941 1.3.3 Awareness of the importance of the correct dosage form

942 1.3.4 Awareness of the importance of the medication history

943 1.3.5 Awareness about asking about allergies

944 1.3.6 Awareness about the importance of asking about other medication

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946 1.4 Patient perception and attitude towards healthcare professionals roles

947 1.4.1 Differentiate between health care professionals role

948 1.4.2 Physicians

949 1.4.2.1 Blame physician

950	1.4.2.2 Physician is always right
951	1.4.3 Pharmacist
952	1.4.3.1 Role of the pharmacist
953	1.4.3.2 Perceive a positive role
954	1.4.3.3 Perceive a negative role
955	1.4.3.4 Based on nationality
956	1.4.3.5 Blame pharmacist
957	
958	1.5 Patient behaviour
959	1.5.1 Self medication
960	1.5.2 Sharing medication
961	1.5.3 Addiction/dependence problem
962	1.5.4 Inappropriate medication use
963	1.5.5 Do not follow instruction
964	1.5.6 Patient pressure to supply medication
965	1.5.7 Noncompliance
966	1.5.8 Patients do not buy medication from pharmacist they do not know
967	1.5.9 Patient test the pharmacist
968	1.5.10 Patient do not want to decide for their selves
969	1.5.11 Trust
970	1.5.11.1 Patients trust pharmacist
971	1.5.11.2 Based on knowledge
972	1.5.11.3 Based on nationality
973	
974	2 Information and communication
975	2.1 Sources of information
976	2.1.1 Pharmacist
977	2.1.2 Physician family, neighbours and friends
978	2.1.3 Internet
979	2.1.4 Package insert
980	2.1.5 Advertisement
981	2.1.6 Media
982	
983	2.2 Type of information requested
984	2.2.1 What it is
985	2.2.2 Direction of use
986	2.2.3 Dose
987	2.2.4 Dosage form
988	2.2.5 What it is taken for
989	2.2.6 Drug interaction
990	2.2.7 Side effects
991	2.2.8 Alternative
992	2.2.9 Cost
993	2.3 Quality of information provided
994	2.3.1 Lack of information
995	2.3.2 Wrong information
996	2.3.3 Understandable information
997	2.3.4 Not patient centred
998	2.3.5 Conflicting information
999	2.3.5.1 Between pharmacists
1000	2.3.5.2 Between pharmacist and physician
1001	2.3.6 Communication between pharmacist and patient
1002	2.3.6.1 Information exchange
1003	2.3.6.1.1 Pharmacist start asking

1004	2.3.6.1.2 Patient start asking
1005	2.3.6.2 Ask about the history
1006	2.3.6.3 Allergic reaction
1007	2.3.6.4 Other medication
1008	2.3.6.5 Privacy
1009	2.3.6.6 Time
1010	2.3.6.7 Third party communicating patient information (family member or other)
1011	2.3.7 Communication between physician and patient
1012	2.3.7.1 Insufficient information gathering from patient
1013	
1014	
1015	3 Comparison between Saudi Arabia community pharmacy practice and other countries
1016	3.1 Pharmacy setting
1017	3.2 Pharmacist practice
1018	3.3 Medication
1019	
1020	4 Medication
1021	
1022	4.1 Medication composition
1023	4.2 Generic substitution
1024	4.3 Illegal supply of medications
1025	4.3.1 Factors that contribute to illegal supply of medication
1026	4.3.2 Consequences of illegal supply
1027	4.3.3 Illegal supply is safe
1028	4.3.4 Illegal supply is risky
1029	4.3.5 Medication that are illegally supplied
1030	4.4 Safe Medication
1031	4.4.1 Paracetamol products
1032	4.4.2 Mebo
1033	4.4.3 Otrivin
1034	4.4.4 Nasonex
1035	4.4.5 Cosmetics
1036	4.4.6 Vitamin C
1037	4.4.7 Aspirin
1038	4.5 Risky medication
1039	4.5.1 Contraceptives
1040	4.5.2 Antibiotics
1041	4.5.3 Cortisone
1042	4.5.4 Asthma medication
1043	4.5.5 Roaccutane
1044	4.5.6 Whiting drugs
1045	4.5.7 Psychotherapeutic agents
1046	4.5.8 Thyroxin
1047	4.5.9 Weight management agents
1048	4.5.10 Creams
1049	4.5.11 Multivitamins
1050	4.5.12 Hormonal replacement therapy
1051	4.5.13 Antihistamine
1052	4.5.14 Medication for cough
1053	4.5.15 Performance enhancing medication in sport
1054	
1055	4.6 Other related medication problems
1056	4.6.1 Medications with unimproved indications
1057	4.6.2 Sources of medication

1058	4.6.3	Availability of medication
1059	4.6.4	Accessibility of medication
1060	4.6.5	Quality of medication
1061	4.6.6	Quantity of medication
1062	4.6.7	Compounding
1063	4.6.8	Counterfeit medications
1064	4.6.9	Expiration date
1065	4.6.10	Bar coding
1066	4.6.11	Pricing
1067	4.7	Herbal medication
1068	4.8	Drug abuse
1069	4.9	Drug misuse
1070	4.10	Medication Storage
1071	4.10.1	Dosage regimen
1072	4.10.1.1	Dose
1073	4.10.1.2	Dosage form
1074	4.11	Medication related problem concerning patient outcome
1075	4.11.1	Duplication of therapy
1076	4.11.2	Adverse drug effects
1077	4.11.3	Medication error
1078	4.11.4	Allergy
1079	4.11.5	Drug interaction
1080	2.11.5.1	Consequences of drug interaction
1081		
1082	5	Pharmacist (related to the pharmacist characteristics and others)
1083	5.1	Lack of knowledge
1084	5.2	The quality of practice/unprofessional practice
1085	5.3	Nationality
1086	5.4	Working hours
1087	5.5	Shortage of staff
1088	5.6	Fraud certificate
1089	5.7	unqualified pharmacist
1090	5.8	Pharmacist busy
1091	5.9	Pharmacist should be proactive
1092	5.10	Ethics and morality
1093	5.11	Stress
1094	5.12	Salary
1095	5.13	Commercial pressure
1096	5.14	Primary role is a n information provider
1097	5.15	Identify drug interaction
1098	5.16	Pharmacovigilance
1099		
1100	6	Pharmacy
1101		
1102	6.1	Pharmacies are accessible
1103	6.2	Sell everything
1104	6.3	Source of medication when government cannot supply enough
1105	6.4	Location and distribution
1106	6.5	Pharmacy owners/managers
1107	6.6	Other personal working in pharmacy
1108	6.7	Pharmacy design and arrangement

1109	6.8 The use of technology
1110	6.8.1 Patient databases
1111	6.8.2 Drug information software's
1112	
1113	7 Organisations and systems
1114	7.1 Role of the Ministry of Health and other organisations
1115	7.2 Regulation for pharmacy practice
1116	7.2.1 The need for regulations
1117	7.2.2 Licence and licensing
1118	7.2.3 Punishment
1119	7.2.4 Lack of enforcement of regulation
1120	7.3 Insurance
1121	7.3.1 The system
1122	7.3.2 The affect of insurance on supply of medication
1123	7.4 Variation between healthcare services
1124	7.5 Pharmaceutical industry
1125	7.6 Multiple health care providers
1126	
1127	8 Physician
1128	8.1 Misdiagnosis
1129	8.2 Physician prescribing behaviour
1130	8.3 Prescribing error
1131	8.4 Handwriting
1132	8.5 Perception of patient that prescription prescribed by patients are safe

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1144 Appendix C

1145 Selected quotes from the focus groups, illustrating examples of the themes that 1146 emerged

Identified themes	Human factor category	Subthemes	Quotes
1. Commercialism and commercial pressure on community pharmacies in Saudi Arabia	External factors	Healthcare system role in commercialism	<p><i>"I mean the proportion of safety increased because the medical insurance makes everyone go to the doctor before they go to the pharmacist, and do not take the treatment directly from the pharmacy."</i> (I-4)</p> <p><i>"Listen, the biggest problem of the medical insurance is that the doctors prescribe medicines they want to sell or will gain benefit from. The most important purpose of most pharmaceutical companies, not all, nowadays, is the sales nothing else, therefore they influence some doctors to prescribe their medicines regardless the patient needs it or not... Ok. This is the main problem of the insurance, because the patient does not pay high amount, therefore the prescription contains medicines that are over the patient's need, prescribed just to be sold, no more"</i> (I-3)</p>
	Organisational and management factors	The role of Pharmacy owners and managers	<i>"Problems between you and the owner arise; he [the owner] asks what happened ... [you] pay a penalty, close the pharmacy and your license is suspended. These problems face us and affect our work."</i> (CPG-4)
	Work environment	Type of pharmacy and its effect on medication safety	<p><i>"We talk about the chain of pharmacy we spend a lot of time to train our pharmacists before going to be behind the counter to dispense medication...Chain of pharmacy or chain group it is easy to implement any regulations"</i> (PG-2)</p> <p><i>"Street pharmacies [independent pharmacies] have more problems because the responsibility is like a burden on the pharmacist's shoulders. He becomes a physician. On the other hand, when I am in a place [where] there is a clinic, half of my time is spent on prescriptions from the clinic, and the physician upstairs is doing his duty, writing the medicine that suits the patient and explaining to him the safety of the medicine. The clinic helps me, but when I work in a street pharmacy, I almost work alone, so I have to exert extra effort to explain to patients."</i> (I-4)</p> <p><i>"...If you will find small pharmacies you will find most of the medication they survive on availability [availability of medication] in chain pharmacies they survive on the biggest bonuses they get."</i> (PG-4)</p>
		Pharmacist working hours	<p><i>"Often, pharmacists find themselves compelled to work in place of their colleagues for extra hours. For example, the average working hours are 15 or 17 hours [a day]. Seventeen hours is a [long time]. The maximum hours we have are 15 hours for certain periods in a month."</i> (CPG-1)</p> <p><i>"I don't expect someone who is frustrated can produce...there should be controls regulating the rights and obligations of the pharmacist. I know someone working for the company (name). He tells me about what is happening he is responsible of choosing the best place to open a pharmacy and he schedules the pharmacist working schedule he says our profits are millions, do not blame the pharmacist they are frustrated."</i> (MPG-5)</p>

		Low salaries	<i>"I don't expect anything from the pharmacist, because all pharmacists are frustrated and this is due to their low salaries and the nature of their work. In a pharmacy, I noticed a pharmacist working in the middle of a hot day on Friday and he used to walk three or four kilometres." (MPG-5)</i>
	Team factors	Physician prescribing behavior	<i>"The medication is prescribed due to a commission, and this has resulted in a loss of confidence between us and physicians." (MPG-7)</i> <i>"Listen, the biggest problem of the medical insurance is that the Doctors prescribe medicines they want to sell or will gain benefit from. The most important purpose of most pharmaceutical companies, not all, nowadays, is the sales nothing else, therefore they influence some doctors to prescribe their medicines regardless the patient needs it or not. Ok." (I-3)</i>
	Task factors	Patient counselling	<i>"The pharmacists' required trait is honesty. He should be honest when giving an opinion or at least not give advice if his advice is for commercial purposes. His positive role is absent here." (MPG-3)</i> <i>"My problem is always that when I go, they give me the best and the latest on the market, that is to say, they do not give me the one appropriate for me. The problem is that they do not try to learn whether it is appropriate or not." (FPG-1)</i>
		Generic substitution	<i>"He sometimes tells you about an alternative if one drug is expensive. I hear him saying, 'its price is seventy, but there is an alternative that is only forty'." (FPG-2)</i> <i>"Price is not the issue, [it is to] prevent you [the patient] from going to other pharmacy" (FPG-5)</i> <i>"When I talk to him and he gives me options, [I think] I came to ask you! Why do you give me options? What do you like? [He asks] Do you want this medicine or is it ok with you if I give you this or this?' No, I want [him] to show me" (FPG-1)</i>
2. Illegal supply of prescription medication by pharmacist	External factors		<i>"But in the past, we had same discussion by the way it is not logic that xxx dose not sell the medication without medications [means prescriptions] while my neighbour is selling without I will be broken and close my business. So, implementing in this time is very important as a chain of pharmacy owner and heading this kind of committee I think very willing we need some kind of cooperation from the Ministry of Health to encourage such way. Of course, I believe always about penalties you need to implement something you need to do it the penalties if there is a punishment for one pharmacy dispensing that everybody will commit with that." (PG-2)</i>
	Individual factors: Pharmacist		<i>"We are pharmacists, we have certificates and we know what to dispense, but there are laws controlling us." (CPG-3)</i> <i>"When you have a patient in front of you needing to be treated, it would be difficult, especially if the patient is poor and needs assistance, not to help him." (CPG-4)</i> <i>"We are not only pharmacists, but also marketers. ... I know why he wants the Liponex, whether he wants to sell or take four or five tablets ... The same happens with the psychological medication ... we may dispense it...Solving the problem of insomnia may not be that he cannot sleep, it may be depression, so we give him antidepressants like Liponex. A week prior to marriage anti-depressants may be needed, and we give Sirolex either for a man or a woman." (CPG-3)</i> <i>"The CPs should not give medications without prescription ... because they are risky." (FPG-8)</i>

3. Lack of enforcement of regulations	External factors	Regulations and regulators	<p><i>"We have three governing bodies in controlling the whole process [medication supply]: one controlling the medication SFDA, one controlling community pharmacy which is MOH, and one controlling the licensing pharmacist, I think either we have one governing body who is controlling the whole process and all effective collaborative efforts between these different agencies." (PG-1)</i></p> <p><i>"I disagree with (PG-1) about what he mentioned about that community pharmacy practice should be under one umbrella. I think this is different because even in Europe the authority who is licensing for the pharmacist is different from the authority licensing for the pharmacy." (PG-2)</i></p> <p><i>"The most important thing is the Ministry of Health, and it is important to inspect on the licenses of pharmacists. Does the pharmacist have a license or not? Does he have a card of the health certificate? There should be a follow-up on medicines in pharmacies. There are medicines sold which are trafficked. This would have to be controlled." (I-3)</i></p>
	Individual factors: Pharmacist	Pharmacist adherence to law and regulations	<p><i>"No professional pharmacist will like to break the law..." (PG-4)</i></p> <p><i>"... When someone comes requesting a combination, I make [prepare the medication as a compound] and hide it as if I am committing a crime." (CPG-4)</i></p> <p><i>"... There is the regulation but they are playing with regulations..." (PG-8)</i></p> <p><i>"Community pharmacy should have a sign state that no prescribed medication should be prescribed without a prescription from a physician we do have it in Arabic written everybody can read, ok. The problem community pharmacy pharmacists although there is a sign they are still selling medications without prescription." (PG-1)</i></p> <p><i>"There is no enforcement on pharmacists for example to label products although the law is saying you have to label products the law is saying you have to dispense with prescription ... [moving his head] they are not doing. The only control that I can say fairly is the narcotic controlled medication." (PG-4)</i></p>
	Medication factors	Counterfeit medication as consequence	<p><i>"I have encountered a lot of counterfeit products It is not medicines but other things, for example, herbs. Many medicines are from natural herbal components, but their origins or their producers are not known, and even there is nothing written on it, and not licensed by the Saudi Ministry of Health." (I-3)</i></p> <p><i>"in Saudi Arabia counterfeit is not a major problem because the system we are going through and the good control of the port in general" (PG-4)</i></p> <p><i>"I think the worst that we suffer regarding medications is fraud ... they could be counterfeit" (FPG-9)</i></p>
4. Healthcare system in KSA	External factors	The fragmented healthcare system	<p><i>"...And I remember one time one patient like he has two different insurance he went to two different doctors and get the same medication from the different insurance ... so we also we need to connect all three [pharmacy, patient, health insurance system] together so we have a system for the insurance for this patient if he has two insurance so he will not abuse this insurance by getting the same kind of medication from different pharmacy or different hospitals." (PG-5)</i></p>
		Lack of patient database in community pharmacies	<p><i>"when PG-6 mentioned about the filing lets go even to institutions in the government you find some patients going to different hospitals with no common filing this is a problem starting from the beginning not from the community which is in the end of the road this is one of the problems I know some people going to different hospitals to get the same medication this is I think a problem. However, I am just wondering about it. This the time I think the MOH to upgrade the behaviour [to implement a filling system]." (PG-2)</i></p> <p><i>"He dispenses medication based on what information you provide him; nothing [is] documented" (MPG-7)</i></p>

	Organizational and management factors	Implementation of technology in community pharmacy	<i>"In America, there is a program contains the name of the medication to be dispensed drug-drug interaction. This system is good and increases the safety of medications and as to the problem of expiration"</i>
5. Patient medication taking behavior		Self-medication	<p>CPG-2: <i>I add the point of the medication, which needs monitoring at intervals such as vitamin D3 and it is of no use being taken randomly without measuring the levels at start. I see them may take the Swiss vitamin D3 (big clap) Each week he takes one bottle just because he thinks he is suffering from osteoporosis</i></p> <p>CPG-4: <i>and this is what is common nowadays</i></p> <p>CPG-1: <i>what is common nowadays is that they suffer from vitamin D deficiency and then take it without taking baseline levels."</i></p> <p><i>"As for the medicine with severe risk that contains cortisone, most women especially here in the KSAuse cortisone [Steroids] for weight gain, [...] Unfortunately, they take it a lot and repeatedly. They may take it monthly for many times." (1- 3)</i></p> <p><i>"Yes, it is the core problem [self-medication]" (MPG-5)</i></p> <p><i>"Regrettably, the issue is the culture of the society, the easiness of obtaining some medications. No need to go far, in the United Arab Emirates, the antibiotic is taken through a prescription whereas in our country, you can take any kind of medications even it is controlled and even from private clinics. "(MPG-6)</i></p>
		Sharing medication	<p>CPG-1: <i>Cooperation, that is, I have a pharmacy at home</i></p> <p>CPG-5: <i>as fruits in the refrigerator.</i></p> <p>Moderator: <i>Well, does that mean all your medications are shared?</i></p> <p>CPG-1: <i>No, not to this extent, may be antibiotic without exaggeration.</i></p> <p>Moderator: <i>Could give me examples?</i></p> <p>CPG-5: <i>When I travel abroad I always have a packet of zithromyx and of course Fevadol, sprays and all medications that I will face a problem their not getting them.</i></p> <p>Moderator: <i>do you share medications with the family, participant 4-3 and participant CPG-4?</i></p> <p>CPG-4: <i>Personally, I am careful with regard to medications, particularly antibiotics and I am careful not to be taken by my children unless for a compelling reason or according to specific instructions. That is, cautiousness with medications, specially, antibiotics. As to sharing, I don't share may be Panadol or painkiller.</i></p>
		Adherence to medication	<i>"Yesterday, I was chatting with one of my friends. He said: while we were moving from house to house, we found a drawer in my mother's room, when we open it; we found it full of medications. She used to bring medication from the hospital and place there so as not to use it. She admits only hypertension and cholesterol; in case of any other medical problems she hides its medication from her sons and daughters." (MPG-6)</i>

6. Patient trust in pharmacists			<p><i>"If working in the government sector, I think they could be honest as most of them are Saudis, with Saudi certificates, the foreigners you cannot know if they have qualification in the field or only salesmen [...] certain places offer fraud certificates, but I do not know more details." (FPG-1)</i></p> <p><i>"We have many cases ... they do not know anything, sometimes they do not even know BID [to be taken two times a day]." (PG-2)</i></p> <p><i>"Many thanks for him now because he refused to give medicine that was inappropriate ... the pharmacist was honest; he seemed to be newly appointed." (FPG-3)</i></p> <p><i>"Patients trust their doctor even if he made a mistake in something; patients never trust anybody else because they fully rely on the doctor." (I-3)</i></p> <p><i>"I see if there is commitment and standards from the pharmacist. [This is] part sincerity. He asks you some questions to make you feel that he is careful, not just give and take some time, they just can get a member of staff to do that." (MPG-2)</i></p>
7. Communication and information exchange		Patient-pharmacist communication	<p><i>"The pharmacist should care about communication with the patient and not get bored questioning the patient. Despite the feeling that the patient does not want to be asked a lot of questions, the pharmacist should do what is best for him ethically. The goal is the patient's benefit." (CPG-1)</i></p> <p><i>"My work depends on communication with my patients." (CPG-4)</i></p> <p><i>"I did not ask, but he was proactive. Just a little information about the medication and I will be thankful, as he is the specialist. I am sure that some of the medications have red lines [cautions]. Even if they are licensed, I need to be informed about the cautions on them." (MPG-2)</i></p> <p><i>"I think education (being proactive) is not the role of the pharmacist. It is impossible to explain everything to everyone. If the patient asks, he should answer; if the patient does not ask, it is not the role of the pharmacist to explain." (MPG-4)</i></p>
		Patient medication information source	<p><i>"I read a package insert with a lot of information warnings and side effects, I always get afraid ... I immediately get my eye glasses and start reading... So even the words they use are harmful, especially when they say 1 in 100,000, some words hurt." (MPG-4)</i></p>
		Factors affecting communication exchange	<p><i>"The pharmacists they are male pharmacists, so the females most of them are sending their driver to get their medication they may not ask questions that can be a communication barrier. Many families send the driver to get the medication" (PG-3)</i></p> <p><i>"He gave him many options, maybe his child's age, I don't know, but he gave him options and explained [things] to him and gave him more time. I kept waiting. When it was my turn, he said to me, 'this is the best, so take it.'" (FPG-1)</i></p> <p><i>"...There is no chair in the reception, in the middle in front of him, a large space so he can put Strepsils and gum. You go abroad; there are chairs for waiting because he knows he will take some of my time to discuss information with the patient before me ... no chairs for waiting, and if you wait, don't expect them to tell you anything." (MPG-5)</i></p>

		Type of information requested by patients from pharmacists	<p>Moderator: what are the most questions that you may ask?</p> <p>MPG-2: the most important matter is to ask him about its side effects</p> <p>MPG-1: Correctly</p> <p>MPG-2: what does the medication do? What is it composed of? Should I continue? Should I continue the dose? May I reduce it? Is it taken when necessary?</p> <p>MPG-7: the important matter that I ask the pharmacist about is: for what problem is this medication taken for? That is in order to know whether the problem is actually a disease or not"</p>
		Information received from pharmacist information compared to information received from physician	<p>"The physician says, 'Because of so and so this is no longer of benefit', and when you go to the pharmacist, he gives another opinion. There is always a struggle inside of us about who to believe." (MPG-1)</p> <p>"This is not the role of the pharmacist. If I take two prescriptions, it is not his role to tell me ... to take this medication with that medication. It is not the responsibility of the pharmacist, not all pharmacists know drug interactions." (MPG-4)</p> <p>The opposite opinion was also expressed: "Why did they study for five years?" (MPG-5)</p>
	Team factors	Communication between pharmacists and physicians	<p>"We also do not know how to communicate with physicians, secondly in order to communicate with him again we have to request his phone number. If I work at a pharmacy, which is far away from the clinic and try calling him my call is divert to an answer machine and they leave on hold the physician does not reply and you start from scratch to call again and stay on hold, you are keen to give the patient the right medication [...] I think there is a safety problem with the prescription trying to communicate with him would be impossible." (CPG-1)</p>

1147 PG Professional Group
1148 FPG Female Pharmacy Users Group
1149 CPG Community Pharmacy Group
1150 MPG Male Pharmacy Users Group
1151 I Interview participant

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